

Biotech Daily

Wednesday May 30, 2018

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: ONCOSIL UP 10%; USCOM DOWN 6%
- * IMMUTEP: 'KEYTRUDA, IMP321 61% OVERALL RESPONSE RATE'
- * CYNATA PLACES \$5.2m WITH FIDELITY
- * IMAGION NANOPARTICLES BIND TO HER2+ TUMOR CELLS IN MICE
- * TELIX, OSAKA UNIVERSITY \$173k GRANT
- * NUHEARA APPOINTS FORCE AUSTRALIA, NEW ZEALAND DISTRIBUTOR
- * ATCOR CHANGES NAME TO CARDIEX, NEW CODE CDX FROM FRIDAY
- * COURT OKAYS PERKINELMER RHS ACQUISITION, DELISTS TODAY
- * BLACKROCK REDUCES TO 6% OF COCHLEAR
- * MAYNE APPOINTS FRANK CONDELLA DIRECTOR
- * ESENSE APPOINTS KOBI ZECHARIA DIRECTOR

MARKET REPORT

The Australian stock market fell 0.48 percent on Wednesday May 30, 2018 with the ASX200 down 28.9 points to 5,984.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 fell, six traded unchanged and one was untraded.

Oncosil was the best, up 1.5 cents or 9.7 percent to 17 cents with 3.4 million shares traded. Immutep and Optiscan climbed more than six percent; Benitec, Osprey and Telix improved more than three percent; Actinogen, Airxpanders, Cynata and Impedimed rose more than two percent; Admedus, Avita, Cochlear and CSL were up more than one percent; with Sirtex up 0.4 percent.

Uscom led the falls, down one cent or 5.6 percent to 17 cents with 19,311 shares traded. Opthea, Orthocell, Prescient and Universal Biosensors fell four percent or more; Cyclopharm, Dimerix and Starpharma lost more than three percent; Medical Developments, Mesoblast and Prana shed more than two percent; Bionomics, Ellex, ITL, Neuren and Reva were down more than one percent; with Clinuvel, Nanosonics, Pro Medicus, Resmed and Volpara down by less than one percent.

IMMUTEP

Immutep says its IMP321 with Keytruda combination trial for melanoma resulted in 11 of 18 patients (61.1%) having an overall response, with two complete responses.

On Monday, Immutep said IMP321 with Keytruda showed six of 18 patients (33%) had an overall response, while nine patients (50%) had tumor shrinkage, with two patients having "complete disappearance of all target lesions" (BD: May 28, 2018).

Today, the company said that the multi-centre, open-label, dose-escalation trial had four cohorts of six patients each testing 1mg, 6mg and 30mg doses in combination with pembrolizumab, marketed as Keytruda.

Immutep said that the data included "more mature data from the first two cohorts and the first data from the third cohort".

The company said that the study showed "long-lasting and durable responses ... in a subset of patients [with an] overall response rate of 61 percent [11 of 18 patients] when tumor size is measured starting from cycle 1 day 1 of pembrolizumab monotherapy and following combination therapy [starting at cycle 5] ... [with] two complete responses related to the combination".

A presentation with the Immutep announcement said that in trials of pembrolizumab alone, 33 percent of 277 ipilimumab-naïve patients and 21 percent of ipilimumab-pre-treated patients had on overall response rate compared to its 61 percent.

The presentation said that 12 patients of 18, or 67 percent, were progression-free at six months compared to 46 percent of the 277 ipilimumab-naïve patients and 34 percent of the ipilimumab-pre-treated patients.

On Monday, Immutep published 'Two ACTive Immunotherapies In Melanoma (TACTImel): Results Of A Phase I Trial With Metastatic Melanoma Patients Treated With A Soluble LAG-3 Receptor (LAG-3Ig Or Eftilagimod Alpha) As An Antigen Presenting (APC) Activator Combined With Pembrolizumab' by chief scientific officer and chief medical officer Dr Frédéric Triebel.

Today, Immutep chief executive officer Marc Voigt said "the new data is very encouraging, further supporting our hypothesis that the combination of efti [IMP321] and pembrolizumab may be a hopeful solution for cancer patients"

"As advancements in PD-1 have enabled breakthroughs in immunotherapy, research is showing that LAG-3 has the potential to take immunotherapy to the next level, enabling more effective cancer treatments," Mr Voigt said.

"We look forward to starting our new efti-pembrolizumab combination program in three different cancer indications as well as the results from the additional Tacti-mel patient cohort in the second half of this year," Mr Voigt said.

Immutep was up 0.2 cents or 6.45 percent to 3.3 cents with 40.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has raised \$5.2 million in a placement to Fidelity International at \$1.275 a share, a 4.5 percent premium to its closing price on May 25, 2018.

Cynata said that following the placement the Bermuda-based Fidelity would hold about 10.0 percent of the company.

The company said that Fidelity was an asset manager that invested \$414.5 billion on behalf of clients in the Asia-Pacific, Europe, the Middle East, and South America.

Cynata said that the placement was under its existing 15 percent placement capacity and the funds would strengthen the balance sheet and support product development activities. The company said that Vesparum Capital was its independent capital markets advisor. Cynata was up three cents or 2.4 percent to \$1.28.

IMAGION BIOSYSTEMS

Imagion says its Magsense nanoparticles bind to HER2+ tumor cells specifically in-vitro and in-vivo.

Imagion said that the nanoparticles "stayed in circulation and provided good clearance in mice, demonstrating preclinical safety evidence".

In a poster for the American Association for Cancer Research Chicago meeting in April, titled 'Detection of HER2+ tumor cells using Magsense Nanoparticles: Safety and Sensitivity' attributed to work with the University of Texas and the Houston-based MD Anderson Cancer Centre, the company said the binding was specific to human epidermal growth factor receptor 2 (HER2) positive cells and the biodegradable nanoparticles did not induce acute or delayed signs of morbidity in mice.

The poster said the nanoparticles detected HER2 positive tumors in mice, the binding and amplitude of magnetic signal was proportional to the level of HER2 expression and the nano-construct was stable in circulation and did not induce a pro-inflammatory response. Imagion said the results supported the first intended use of the Magsense platform for the in-vivo detection of HER2 amplified tumor cells and based on the preclinical data, the Magsense anti-HER2 nanoparticles were being produced along with a research and development version for an early stage research clinical trial.

The company said that Magsense was an in-vivo diagnostic for the detection of primary and metastatic disease, comprising tumor-targeting super-para-magnetic iron oxide nanoparticles and a device capable of distinguishing the magnetic signatures of free particles flowing through blood from those that reach and bind to their intended target. Imagion said that the first intended use would be to test the ability of Magsense nanoparticles labeled with an anti-HER2 antibody to detect HER2+ breast cancer in the sentinel and axillary lymph nodes of patients previously confirmed with HER2+ disease. Imagion was unchanged at 6.4 cents.

TELIX PHARMACEUTICALS

Telix says it has a research collaboration with Osaka University Graduate School of Medicine's Department of Nuclear Medicine and Tracer Kinetics.

Telix said that collaboration was partly-funded through a pilot grant from the Japan Science and Technology Agency with \$US130,000 (\$A173,332) provided for initial proof-of-concept research, which would pave the way to clinical studies.

The company said the matched-funding grant would support exploration of the feasibility of using several of its targeting agents with astatine, an alpha-emitter "capable of significantly altering the tumor micro-environment when attached to a molecular-targeting agent that is specific for cancer cells".

Telix was up two cents or 3.1 percent to 67 cents.

<u>NUHEARA</u>

Nuheara says that it has appointed the Perth, Western Australia Force Technology as a distributor for its hearing products in Australia and New Zealand.

Nuheara said that Force had more than 4,000 reseller partners including Telstra, Harvey Norman, Optus, Retravision, JB Hi-fi and Officeworks.

Nuhear chief executive officer Justin Miller said that Force had "proven success of distributing mobile lifestyle products from leading brands to resellers in Australia and New Zealand".

Nuheara fell 0.3 cents or 3.3 percent to 8.7 cents with 7.9 million shares traded.

CARDIEX (FORMERLY ATCOR MEDICAL)

Atcor says its name has been changed officially to Cardiex and it will begin trading under the code CDX from the start of trade on Friday, June 1, 2018.

Cardiex chief executive officer Craig Cooper said the change of name "reflects our focus on becoming a global health technology company as we rapidly move to grow our current business as well as expand into other health markets".

"Our current Atcor cardiovascular medical device business will initially continue under the Atcor brand as an operating division of Cardiex while over the next few months we implement a new corporate identity platform representing our new brand, product, and marketing focus," Mr Cooper said.

Cardiex was up 0.1 cents or four percent to 2.6 cents.

RHS (FORMERLY REPRODUCTIVE HEALTH SCIENCE)

RHS says the Federal Court of Australia has approved the scheme of arrangement for Perkinelmer to complete the acquisition today.

In February RHS said that Perkinelmer would acquire it for 28 cents a share, valuing the company at \$25,177,735 (BD: Feb 26, 2018).

RHS said that the court orders were expected to be lodged with the Australian Securities and Investments Commission today, May 30, 2018, with its shares expected to be suspended from trading at the close of trading today and scheme completion on June 14, 2018.

RHS last traded at 27.5 cents.

COCHLEAR

Blackrock Investment Management has reduced its substantial shareholding in Cochlear from 4,116,410 shares (7.16%) to 3,545,258 shares (6.16%).

Blackrock said that between July 24, 2017 and May 25, 2018 it bought and sold shares in more than 2,700 trades at prices ranging from \$140.15 to \$199.01.

The company previously said the registered holders included Bank of New York melon, JP Morgan Chase, State Street Bank New York and Singapore, Northern Trust UK, RBC Dexia, UBS Zurich, Citigroup, BNP Paribas, Bank of America Merrill Lynch, Goldman Sachs, Morgan Stanley, National Australia Bank and HSBC (BD: Jul 26, 2017). Cochlear was up \$3.15 or 1.6 percent to \$198.32 with 177,799 shares traded.

MAYNE PHARMA GROUP

Mayne says it has appointed Frank Condella as a director, effective immediately. Mayne said the US-based Mr Condella had more than 30 years' experience in executive roles in the pharmaceutical industry, most recently as the Boston-based Juniper Pharmaceuticals chief executive officer.

The company said that previously Mr Condella was Skyepharma PLC chief executive officer and Ivax head of European operations, Faulding Pharmaceuticals chief executive officer Roche head of specialty care products at Roche and Pfizer American Home Products Lederle Standard Products general-manager.

Mayne said that Mr Condella held a Bachelor of Science and a Master of Business Administration from Boston's Northeastern University.

Mayne was up 2.5 cents or 3.4 percent to 77 cents with 7.5 million shares traded.

ESENSE-LAB

Esense says it has appointed Kobi Zecharia as a non-executive director. Esense said that Mr Zecharia had been the chief executive officer, chairman, director and co-founder of several high-technology companies, as well as an investment banker. The company said that Mr Zecharia had worked for Israel's Poalim Capital Markets and Investments, Leumi and Co Investment Bank, Israel Discount Capital Markets and Investments and was the chief executive officer of Zeler Eblagon Underwriting and Investment, as well as Menorah-Gaon Underwriting and Investment.

Esense said that Mr Zecharia had raised more than \$US1 billion for established companies and start-ups.

The company said that Mr Zecharia held a Bachelor of Arts from the Be'er Sheva-based Ben Gurion University and a Master of Business Administration from Tel Aviv's Bar-Ilan University.

Esense fell 0.3 cents or 4.1 percent to seven cents.